

References

1. Albert, C.M., C.H. Hennekens, C.J. O'Donnell, U.A. Ajani, V.J. Carey, W.C. Willett, J.N. Ruskin, and J.E. Manson. Fish consumption and risk of sudden cardiac death. *Journal of the American Medical Association*. 1998; 279(1):23-28.
2. Albert, C.M., H. Campos, M.J. Stampfer, P.M. Ridker, J.E. Manson., W.C. Willett, and J. Ma. Blood levels of long-chain n-3 fatty acids and the risk of sudden death. *The New England Journal of Medicine*. 2002; 346(15):1113-1118.
3. Angerer, P., W. Kothny, S. Störk, and C. von Schacky. Effect of dietary supplementation with ω-3 fatty acids on progression of atherosclerosis in carotid arteries. *Cardiovascular Research*. 2002; 54(1):183-190.
4. Bang, H.O., J. Dyerberg, and H.M. Sinclair. The composition of the Eskimo food in north western Greenland. *American Journal of Clinical Nutrition*. 1980;33(12):2657-2661.
5. Bucher, H.C., P. Hengstler, C. Schindler, and G. Meier. N-3 polyunsaturated fatty acids in coronary heart disease: a meta-analysis of randomized controlled trials. *American Journal of Medicine*. 2002;112(4):298-304.
6. Burr, M.L., A.M. Fehily, J.F. Gilbert, S. Rogers, R.M. Holliday, P.M. Sweetnam, P.C. Elwood, and N.M. Deadman. Effects of changes in fat, fish, and fibre intakes on death and myocardial reinfarction: Diet and Reinfarction Trial (DART). *Lancet*. 1989;2(8666):757-761.
7. Burr, M.L., P.M. Sweetham, and A.M. Fehily. Letter to the Editor. Diet and reinfarction. *European Heart Journal*. 1994;15(8):1152-1153.
8. Connor, W.E. Importance of n-3 fatty acids in health and disease. *American Journal of Clinical Nutrition*. 2000;71(1 Suppl):171S-175S.
9. Consumer Reports. Omega-3 Oil. Fish or Pills? Pages 30-32, July 2003
10. de Lorgeril, M., P. Salen, P. Defaye, P. Mabo, and F. Paillard. Dietary prevention of sudden cardiac death. *European Heart Journal*. 2002;23(4):277-285.
11. Dyerberg, J., H.O. Bang, E. Stoffersen, S. Moncada, and J.R. Vane. Eicosapentaenoic acid and prevention of thrombosis and atherosclerosis? *Lancet*. 1978;2(8081):117-119.
12. Federal Judicial Center, Reference Manual on Scientific Evidence, Second Edition, 2000, page 93

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REF1

13. Finnegan, Y.E., A.M. Minihane, E.C. Leigh-Firbank, S. Kew, G.W. Meijer, R. Muggli, P.C. Calder, and C.M. Williams. Plant- and marine-derived n-3 polyunsaturated fatty acids have differential effects on fasting and postprandial blood lipid concentrations and on the susceptibility of LDL to oxidative modification in moderately hyperlipidemic subjects. *American Journal of Clinical Nutrition.* 2003;77(4):783-795.
14. Foran, S.E., J.G. Flood, and K.B. Lewandrowski. Measurement of mercury levels in concentrated over-the-counter fish oil preparations. Is fish oil healthier than fish? *Arachives of Pathology & Laboratory Medicine.* 2003;127:1603-1605.
15. Ghafoorunissa, A. Vani, R. Laxmi, and B. Sesikeran. Effects of dietary α -linolenic acid from blended oils on biochemical indices of coronary heart disease in Indians. *Lipids.* 2002;37(11):1077-1086.
16. Gillum, R.F., M. Mussolini, and J.H. Madans. The relation between fish consumption, death from all causes, and incidence of coronary heart disease. The NHANES I Epidemiologic Follow-up Study. *Journal of Clinical Epidemiology.* 2000;53(3):237-244.
17. GISSI-Prevenzione Investigators. Dietary supplementation with n-3 polyunsaturated fatty acids and vitamin E after myocardial infarction: results of the GISSI-Prevenzione trial. *Lancet.* 1999; 354:447-455.
18. Goel, D.P., T.G. Maddaford, and G.N. Pierce. Effects of ω -3 polyunsaturated fatty acids on cardiac sarcolemmal Na^+/H^+ exchange. *American Journal of Physiology-Heart and Circulatory Physiology.* 2002;283(4):H1688-H1694.
19. Guallar, E., M.I. Sanz-Gallardo, P. van't Veer, P. Bode, A. Aro, J. Gomez-Aracena, J.D. Kark, R.A. Riemersma, J.M. Martin-Moreno, and F.J. Kok, for the Heavy Metals and Myocardial Infarction Study Group. Mercury, fish oils, and the risk of myocardial infarction. *The New England Journal of Medicine.* 2002;347:1747-1754.
20. Hallgren, C.G., G. Hallmans, J.H. Jansson, S.L. Marklund, F. Huhtasaari, A. Schütz, U. Strömb erg, B. Vessby, and S. Skerfving. Markers of high fish intake are associated with decreased risk of a first myocardial infarction. *British Journal of Nutrition.* 2001;86(3):397-404.
21. Hu, F.B., L. Bronner, W.C. Willett, M.J. Stampfer, K.M. Rexrode, C.M. Albert, D. Hunter, and J.E. Manson. Fish and ω -3 fatty acid intake and risk of coronary heart disease in women. *Journal of the American Medical Association.* 2002;287(14):1815-1821.

22. Hu, F.B., E. Cho, K.M. Rexrode, C.M. Albert, and J.E. Manson. Fish and long-chain ω-3 fatty acid intake and risk of coronary heart disease and total mortality in diabetic women. *Circulation*. 2003;107(14):1852-1857.
23. Institute of Medicine of the National Academies, Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids. Chapter 8, "Dietary Fats: Total Fat and Fatty Acids," and Chapter 11, "Macronutrients and Healthful Diets," (National Academy Press 2002).
24. Kris-Etherton, P.M., W.S. Harris, and L.J. Appel; American Heart Association. Nutrition Committee. Fish consumption, fish oil, omega-3 fatty acids, and cardiovascular disease. *Circulation*. 2002;106(21):2747-2757.
25. Krokan, H.E., K.S. Bjerve, and E. Mørk. The enteral bioavailability of eicosapentaenoic acid and docosahexaenoic acid is good from ethyl esters as from glyceryl esters in spite of lower hydrolytic rates by pancreatic lipase in vitro. *Biochimica et Biophysica Acta*. 1993;1168(1):59-67.
26. Laidlaw, M. and B.J. Holub. Effects of supplementation with fish oil-derived n-3 fatty acids and γ-linolenic acid on circulating plasma lipids and fatty acid profiles in women. *American Journal of Clinical Nutrition*. 2003;77(1):37-42.
27. Leaf, A., J.X. Kang, Y.F. Xiao, and G.E. Billman. Clinical prevention of sudden cardiac death by n-3 polyunsaturated fatty acids and mechanism of prevention of arrhythmias by n-3 fish oils. *Circulation*. 2003;107(21):2646-2652.
28. Lemaitre, R.N., I.B. King, D. Mozaffarian, L.H. Kuller, R.P. Tracy, and D.S. Siscovick. n-3 Polyunsaturated fatty acids, fatal ischemic heart disease, and nonfatal myocardial infarction in older adults: the Cardiovascular Health Study. *American Journal of Clinical Nutrition*. 2003; 77(2):319-325.
29. Leng, G.C., A.J. Lee, F.G. Fowkes, R.G. Jepson, G.D. Lowe, E.R. Skinner, and B.F. Mowat. Randomized controlled trial of gamma-linolenic acid and eicosapentaenoic acid in peripheral arterial disease. *Clinical Nutrition*. 1998;17(6):265-271.
30. Marchioli, R., F. Barzi, E. Bomba, C. Chieffo, D. Di Gregorio, R. Di Mascio, M.G. Franzosi, E. Geraci, G. Levantesi, A.P. Maggioni, L. Mantini, R.M. Marfisi, G. Mastrogiovanni, N. Mininni, G.L. Nicolosi, M. Santini, C. Schweiger, L. Tavazzi, G. Tognoni, C. Tucci, and F. Valagussa; GISSI-Prevenzione Investigators. Early protection against sudden death by n-3 polyunsaturated fatty acids after myocardial infarction: time-course analysis of the results of the Gruppo Italiano per lo Studio della Sopravvivenza nell'Infarto Miocardico (GISSI)-Prevenzione. *Circulation*. 2002;105(16):1897-1903.

31. Maresta, A., M. Balduccielli, E. Varani, M. Marzilli, C. Galli, F. Heiman, M. Lavezzari, E. Stragliotto, and R. De Caterina; ESPRIT Investigators. Prevention of postcoronary angioplasty restenosis by omega-3 fatty acids: main results of the Esapent for Prevention of Restenosis ITalian Study (ESPRIT). *American Heart Journal*. 2002;143(6):E5.
32. Mozaffarian, D., R.N. Lemaitre, L.H. Kuller, G.L. Burke, R.P. Tracy, and D.S. Siscovick; Cardiovascular Health Study. Cardiac benefits of fish consumption may depend on the type of fish meal consumed: the Cardiovascular Health Study. *Circulation*. 2003;107(10):1372-1377.
33. Nilsen, D.W., G. Albrektsen, K. Landmark, S. Moen, T. Aarsland, and L. Woie. Effects of a high-dose concentrate of n-3 fatty acids or corn oil introduced early after an acute myocardial infarction on serum triacylglycerol and HDL cholesterol. *American Journal of Clinical Nutrition*. 2001;74(1):50-56.
34. ORC Macro. Consumer reactions to the draft advisory on methyl mercury in fish. Focus Group Research. Summary of key findings. U.S. Food and Drug Administration. March 2003.
35. Osler, M., A.H. Andreasen, and S. Hoidrup. No inverse association between fish consumption and risk of death from all-causes, and incidence of coronary heart disease in middle-aged, Danish adults. *Journal of Clinical Epidemiology*. 2003;56(3):274-279.
36. Pepe, S. and P.L. McLennan. Cardiac membrane fatty acid composition modulates myocardial oxygen consumption and postischemic recovery of contractile function. *Circulation*. 2002; 105(19):2303-2308.
37. Rissanen, T., S. Voutilainen, K. Nyyssönen, T.A. Lakka, and J.T. Salonen. Fish oil-derived fatty acids, docosahexaenoic acid and docosapentaenoic acid, and the risk of acute coronary events: the Kuopio Ischaemic Heart Disease Risk Factor Study. *Circulation*. 2000;102(22):2677-2679.
38. Salonen, J.T., K. Seppänen, K. Nyyssönen, H. Korpela, J. Kauhanen, M. Kantola, J. Tuomilehto, H. Esterbauer, F. Tatzber, and R. Salonen. Intake of mercury from fish, lipid peroxidation, and the risk of myocardial infarction and coronary, cardiovascular, and any death in Eastern Finnish men. *Circulation*. 1995;91:645-655.
39. Sacks, F.M., P.H. Stone, C.M. Gibson, D.I. Silverman, B. Rosner, and R.C. Pasternak. Controlled trial of fish oil for regression of human coronary atherosclerosis. HARP Research Group. *Journal of the American College of Cardiology*. 1995;25(7):1492-1498.

40. Singh, R.B., M.A. Niaz, J.P. Sharma, R. Kumar, V. Rastogi, and M. Moshiri. Randomized, double-blind, placebo-controlled trial of fish oil and mustard oil in patients with suspected acute myocardial infarction: the Indian Experiment of Infarct Survival—4. *Cardiovascular Drugs and Therapy*. 1997;11(3):485-491.
41. Siscovick, D.S., R.N. Lemaitre, and D. Mozaffarian. The fish story: a diet-heart hypothesis with clinical implications: n-3 polyunsaturated fatty acids, myocardial vulnerability, and sudden death. *Circulation*. 2003;107(21):2632-2634.
42. Spilker, B. *Guide to Clinical Studies*. Raven Press, New York, New York, 1991.
43. Thies, F., J.M. Garry, P. Yaqoob, K. Rerkasem, J. Williams, C.P. Shearman, P.J. Gallagher, P.C. Calder, and R.F. Grimble. Association of n-3 polyunsaturated fatty acids with stability of atherosclerotic plaques: a randomized controlled trial. *Lancet*. 2003;361(9356):477-485.
44. Torres, I.C., L. Mira, C.P. Ornelas, and A. Melim. Study of the effects of dietary fish intake on serum lipids and lipoproteins in two populations with different dietary habits. *British Journal of Nutrition*. 2000;83(4):371-379.
45. United States Department of Agriculture and United States Department of Health and Human Services. *Nutrition and Your Health: Dietary Guidelines for Americans*. Fifth Edition, 2000. Home and Garden Bulletin No. 232, 2000.
46. United States Department of Health and Human Services. *Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III)*. Executive Summary. NIH Publication No. 01-3670. 2001.
47. von Schacky, C., P. Angerer, W. Kothny, K. Theisen, and H. Mudra. The effect of dietary ω-3 fatty acids on coronary atherosclerosis. A randomized, double-blind, placebo-controlled trial. *Annals of Internal Medicine*. 1999;130(7):554-562.
48. Woodman, R.J., T.A. Mori, V. Burke, I.B. Puddey, G.F. Watts, and L.J. Beilin. Effects of purified eicosapentaenoic and docosahexaenoic acids on glycemic control, blood pressure, and serum lipids in type 2 diabetic patients with treated hypertension. *American Journal of Clinical Nutrition*. 2002;76(5):1007-1015.
49. Yoshizawa, K., E.B. Rimm, J.S. Morris, V.L. Spate, C.C. Hsieh, D. Spiegelman, M.J. Stampfer, and W.C. Willett. Mercury and the risk of coronary heart disease in men. *The New England Journal of Medicine*. 2002;347:1755-1760.